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IN THE

Supreme Court of the United States

OCTOBER TERM, 1965

No. 372

ALLAN DRUG CORPORATION, *Petitioner*

v.

UNITED STATES OF AMERICA, *Respondent*

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE TENTH CIRCUIT

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INDEX

	Page
OPINIONS BELOW	1
JURISDICTION	1
QUESTION PRESENTED	2
STATUTES INVOLVED	2
STATEMENT	2
REASONS FOR GRANTING WRIT	5
CONCLUSION	13
APPENDIX A—STATUTES	13
APPENDIX B—OPINION BELOW	17
APPENDIX C—CONFLICTING OPINION	32

CITATIONS

CASES:	Page
A. O. Anderson & Co. v. United States, 284 Fed. 542 (9th Cir. 1922)	10
Buticaps, Inc. v. United States, 252 F.2d 634	6, 10, 11
United States v. 9 Barrels of Butter, 241 Fed. 499 (S.D.N.Y. 1917)	10
United States v. 2 Cans of Oil of Sweet Birch and 3 cans of Oil of Gaultheria, 268 Fed. 866 (S.D.N.Y 1960)	10

STATUTES: Page

Federal Food, Drug and Cosmetic Act,
Section 201(p)(1) [21 U.S.C. 321(p)(1)] 2, 4, 5, 6
Section 304(a) [21 U.S.C. 334(a)] 2
Section 304(d) [21 U.S.C. 334(d)] 2, 5, 6
Section 502(a) [21 U.S.C. 352(a)] 1, 2, 4, 6
21 U.S.C. 505, Reg. 130.4 12
21 U.S.C. 505, Reg. 130.9 12
28 U.S.C. 1254(1) 1
New Drug Act of 1962, 21 U.S.C. 355 ..... 2, 4, 5, 13
Drug Amendments of 1962, Sec. 107(c)(4) (21 U.S.C.A. Supp. Footnote following Sec. 321) 2, 4, 5, 11
Food and Drugs Act of 1906 (S. 88, 59th Cong. 1st Sess.) 8
1938 Food & Drug Act, Sec. 304(d) 10

MISCELLANEOUS:

Fifth Amendment, U. S. Constitution 5, 6
H.R. 6295, 58th Cong. 2d Sess., January 20, 1904, Sec. II 7, 8
Cong. Rec. 936 (58th Cong. 2nd Sess.) 8
Cong. Rec. 126 (58th Cong., 3rd Sess.) 8
Cong Rec. 898 (59th Cong., 1st Sess.) 8
Cong. Rec. 9380, 9735-37 (59th Cong., 1st Sess.) ... 9
21 C.F.R. 130.3 ..... 4, 5

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The petitioner prays that a writ of certiorari issue to review the judgment of the United States Court of Appeals for the Tenth Circuit, entered in the above case on February 18, 1965, reversing the judgment of the District Court for the District of Colorado, wherein the District Court entered an order authorizing relabeling of a product which had been found to be misbranded under Section 502(a) of the Food, Drug and Cosmetic Act, 21 U.S.C. 352(a).

Citations To Opinions Below

The majority and dissenting opinions of the Circuit Court of Appeals are unreported and are printed in Appendix B hereof. (infra, page 17).

Jurisdiction

The judgment of the Court of Appeals of the Tenth Circuit was entered on February 18, 1965. A timely petition for rehearing filed on April 8, 1966 was denied on April 29, 1966. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

Question Presented

The issues in this case are (1) whether a drug found to be misbranded under Section 502(a) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 352(a) for the reason that the labeling was false or misleading because the drug was not effective for the use recommended in its labeling, becomes a "new drug" as defined in 21 U.S.C. 201(p), when its labeling is revised to recommend the same use in more limited terms, (2) whether or not a District Court can order salvage proceedings under 21 U.S.C. 334(d), and (3) whether or not a Circuit Court of Appeals may find that a product is a "new drug" and subject to the procedures of the New Drug Act of 1962, 21 U.S.C. 355, when in fact there has been no finding made by the trial court, nor evidence taken by the trial court as to whether or not said product is in fact a "new drug" as defined by the Act.

Statutes Involved

The statutory provisions involved are Sections 201(p)(1), 304(a), 304(d), and 502(a) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321(p)(1), 334(a), 334(d), 352(a), and Section 107(c)(4)) of the Drug Amendments of 1962 (21 USCA Supp. Footnote foll'g Sec. 321). They are printed in Appendix A (infra, pages 13 to 16).

Statement

This proceeding arises from two consolidated seizure actions brought under the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 334(a), against a product owned by the petitioner known as "Halsion, A Plan of Medication and Care for Acne and Pimples." The action in Colorado was filed May 27, 1963; the California action was filed March 30, 1964. The jurisdiction of the District Court was invoked because the action arose under 21 U.S.C. 352(a).

The issues framed by the pre-trial order were (1) Was the Halsion Plan an adequate and effective treatment for acne and pimples; (2) Was there unanimity of opinion as to the

proven value of the "Halsion Plan"; (3) Did other remedies provide a temporary mask for skin disorders while the Halsion Plan provided lasting relief; (4) Did the Halsion tablet represent a new type of internal medication and, in conjunction with the Halsion Plan, a scientific breakthrough in the treatment of acne and pimples. (R. 13)

After trial the District Court found that the representations on the product's labeling were misleading in the following respects:

> "(a) The 'Halsion Plan' in and of itself is not an adequate and effective remedy for the treatment for acne and pimples.
>
> "(b) There is not a unanimity of opinion in the medical profession as to the proven value of the 'Halsion Plan', either including or excluding the taking of the Halsion pills, as an effective treatment for acne and pimples.
>
> "(c) Neither the Halsion Plan nor the Halsion pills consist of 'a revolutionary new vitamin formula for internal medication' in the treatment of acne and pimples. Vitamins are prescribed by some members of the medical profession as a part of the treatment for acne and pimples. The use of vitamins for this purpose began about thirty years ago.
>
> "4. The 'Halsion Plan' may be of some benefit in mild cases of acne and pimples, and the measures prescribed in the Plan are used by some members of the medical profession, in whole or in part, in conjunction with other measures and treatments which the physician may deem to be indicated. There is no evidence that any members of the medical profession use or recognize the Halsion Plan in and of itself as an adequate and effective treatment for acne and pimples." (R. 26-47)

The District Court concluded that the labeling of Halsion tablets was false and misleading and was misbranded in

violation of 21 U.S.C. 352. (R. 27) A Decree of Condemnation was entered on August 28, 1964, by the trial court authorizing the claimant to post bond and relabel the condemned articles under supervision of a duly authorized representative of the Secretary of Health, Education and Welfare. (R. 29) The trial court reserved jurisdiction to allow the Claimant to file a motion with the Court for appropriate orders regarding labeling in the event the Claimant and the Food and Drug Administration officials could not resolve the manner in which relabeling should be accomplished. (R. 30)

The Claimant and representatives of the Food and Drug Administration met on September 11, 1964, at which time the government representatives advised the Claimant that no relabeling of the product would be acceptable to that agency. By letter directed to Claimant's attorney the Food and Drug Administration raised numerous objections to the proposed relabeling submitted by the Claimant contending the proposed relabeling did not conform to the guidelines given by the trial court (R. 194) and primarily objecting to relabeling for the reason that the product was a "new drug" as defined by Section 201(p) of the Act and had lost its exemption under the "grandfather clause" of the Drug Amendments of 1962 (Sec. 107(c)(4) of the Drug Amendments of 1962) since a revised labeling would be necessary as a result of the trial court's ruling that the labeling was false and misleading. (R. 52)

The matter was presented to the trial court by motion on October 2, 1964, and the court ruled that the product may be relabeled and dispensed without compliance with the Drug Amendments of 1962, 21 U.S.C. 355(i) and 21 C.R.F. 130.3, since the required relabeling does not *extend* the uses under conditions prescribed, recommended, or suggested in the labeling with respect to the drug on October 9, 1962. (Emphasis supplied) (R. 59)

The trial court then ordered the approval of a new label for the condemned product which limited the representa-

tions of the effectiveness of the Plan to the general phrase "may be helpful in mild cases of acne-pimples" and omitted any reference to the product being an adequate and effective treatment, unanimity of opinion as to the proven value of the Plan, lasting relief from the Plan, or that Halsion was a scientific breakthrough in the treatment of acne-pimples. (R. 59) (Footnote 8 of Appendix B)

On appeal to the Circuit Court of Appeals the government argued that the product with revised labeling, even though for the same use—acne—as prescribed in the product's label on the cut-off date (October 9, 1962), was no longer protected by the "grandfather clause", (Sec. 107(c)(4) of the Drug Amendments of 1962), and must comply with the Drug Amendment of 1962, 21 U.S.C. 355(i) and 21 C.R.F. 130.3. The majority opinion of the appellate court in reversing the District Court has held that a revision in labeling, however slight, forfeits "grandfather protection". The dissenting opinion of Judge Seth supports the time-honored authority of the trial judge to order salvage proceedings as authorized by 21 U.S.C. 334(d) and further holds that 21 U.S.C. 321(p)(1) is not applicable to involuntary proceedings as a part of a court's salvage order.

Reasons for Granting the Writ

1. The decision of the Court below is directly in conflict with the provisions of the Fifth Amendment to the United States Constitution, which provides in part:

> "No person shall be deprived of life, liberty, or property, without due process of law."

In this case, the Appellate Court has concluded that the product owned by the petitioner is a new drug as defined by 21 U.S.C. 201(p), yet there has been no hearing on that subject before any trial court nor has the petitioner been permitted to introduce evidence regarding that issue.

The petitioner has been denied a hearing on the question of whether or not its product is or is not a new drug as defined by the Act, and such denial is a violation of the Fifth Amendment to the Constitution of the United States.

It does not follow logically that a drug is a "new drug" under changed labeling and therefore subject to new drug procedures just because it has been found to be mislabeled under Section 502(a) of the Act. To be a "new drug", the drug must be shown to come within the definition of Section 201(p). To come within that definition it must be shown to be not GRAS (Generally Recognized As Safe), or not GRAE (Generally Recognized As Effective), for the conditions in its labeling. When, as here, the issue involves a revised labeling or, more precisely, the labeling being revised under the Court's supervision in a Section 304(d) salvage proceeding, the drug must be shown to be not GRAS or not GRAE under that labeling; the fact that it was not GRAS or not GRAE under discarded or prohibited labeling is not determinative. The fact that the drug was held misbranded under Section 502(a) because a "plan" of which its use formed a part was not in and of itself an "adequate and effective treatment" for acne pimples to the extent claimed (R. 26-27), does not mean that under that labeling, much less the revised labeling, the drug was held to be not GRAE under Section 201(p). It is in the light of the particular labeling that a drug must be shown to be a new drug and unless it is determined after hearing, it is a deprivation of the constitutional rights of the petitioner to hold as a matter of law that it cannot be sold without an approved NDA application.

2. The decision of the Court below is in direct conflict with the decision of the Court of Appeals for the District of Columbia in *Buticaps, Inc. v. United States,* 252 F.2d 634. A copy of the decision of the Court of Appeals for the District of Columbia is appended hereto in Appendix C. The decision of the court below is further in conflict with the history of drug legislation in the United States.

While the first proposal for a Federal Food and Drug Act contained provisions for the condemnation of adulterated or misbranded products, they did not expressly authorize the District Courts to permit the return of a condemned product to the owner for reconditioning and subsequent sale. The issue of the authority of the District Courts emerged in the debate on a later proposal, H.R. 6295, 58th Cong., 2d Sess., on January 20, 1904. Section II of H.R. 6295, provided in relevant part as follows:

> "And if such article is condemned as being adulterated the same shall be disposed of as the said court may direct . . . "

Although Section II did not in terms authorize the return of a condemned product to its owner, its language provoked the following exchange on the floor of the House:

> "Mr. Clark. . . . Mr. Chairman, that is a most remarkable proposition, that the courts of the United States shall pronounce, judicially that a thing if sold in violation of this law by reason of adulteration can then proceed to the sale of the very same identical thing, by a public authority, the sale of which is prohibited to a private citizen. It is an outrage on common sense and ordinary decency. There is not a man living that can justify it.
>
> "Mr. Mann. Will the gentleman from Missouri pardon me?
>
> "Mr. Clark. Yes.
>
> "Mr. Mann. Suppose milk is being sold as good milk, and it is confiscated as being skim milk. Is there any reason why it should not be sold as skim milk? . . . Mr. Chairman, the words that the gentleman moves to strike out do not require the sale of the article that is found to be adulterated.
>
> "Mr. Clark. The words authorize the sale.
>
> "Mr. Mann. It authorizes the court to dispose of this.

> The illustration that I gave the gentleman disposes of this proposition. The article may be offered as cream and it may be simply milk. If it is offered as cream and it is in fact only milk, it is subject to seizure. There is no reason in the world why it should not be sold as milk." Cong. Rec. 936.

On December 12, 1904, Senator Heyburn proposed an amendment to a Senate substitute for H.R. 6295 to clarify the authority of the District Courts in condemnation proceedings. Cong. Rec. 126 (58th Cong., 3rd Sess.) The amendment, which became part of the bill that was enacted as the Food and Drugs Act of 1906 (S. 88, 59th Congress, 1st Sess.), read:

> "*Provided, however,* that upon the payment of the costs of such libel proceedings and the execution and delivery of a good and sufficient bond to the effect that such article shall not be sold or otherwise disposed of contrary to the provisions of this act, or the possession, the court may by order direct that such articles be delivered to the owner thereof." Cong. Rec. 898.

During the 1906 debate on the final bill, S. 88, Senator Spooner inquired about the language permitting the disposition of condemned articles "by destruction or sale, as the said Court may direct." Senator Heyburn, the author of the bill, responded:

> "Mr. President, the Senator, I think, has not observed that the expressions and the alternatives, and that it is left to the court to determine what would be the appropriate disposition to be made of the Article. . . .
>
> "Mr. Spooner. I have not conceived it possible that Congress should be authorizing a court . . . to condemn an article because of a poison in it deleterious to the health of any human being, to sell it in any jurisdiction.
>
> "Mr. Heyburn. I think the bill does not provide that

> the court shall have that right any more than the right to exercise such judgment. . . . It might be that the law would not find it necessary to confiscate the article, but to simply require the party to keep it out of the general mass of foods.
>
> "Mr. Fulton. I call attention of the Senator who has the floor to this language:
>
> And if such article is condemned as being *adulterated or misbranded*
>
> . . . to be poisonous or of a deleterious character is one thing, and adulterated or misbranded is another; and it would be a wise discretion of the court to order them to be condemned, destroyed, or sold.
>
> "Mr. Heyburn. That is in the alternative. . . .
>
> "Mr. McCumber. . . . There is nothing to compel, and I hardly think that the court take it in the spirit of the law, would construe that he had authority to sell under this bill or to order the sale of poisonous or deleterious matter. By using the conjunction "or" there gives him the right to either destroy it, allow the purchaser to take it back by giving a bond, or to sell it if such an article as can be sold for what it is." Cong. Rec. 2735-36.

After the House passed a bill which differed from the Senate version in several respects, including its omission of Senator Heyburn's proviso, the Conference Committee reported a bill containing in Section 10 provisions for salvage in the form ultimately enacted. (Cong. Rec. 9380, 9735-37 (59th Congress, First Sess.).) The provision read as follows:

> "And if such article is condemned as being adulterated or misbranded, or of poisonous or deleterious character, within the meaning of this act, the same shall be disposed of by destruction or sale, as the said court may direct, and the proceeds thereof, if sold, less the legal costs and charges, shall be paid

> into the Treasury of the United States, but such goods shall not be sold in any jurisdiction contrary to the provisions of this act or the laws of that jurisdiction: *Provided, however,* That upon the payment of the costs of such libel proceedings and the execution and delivery of a good and sufficient bond of the effect that such article shall not be sold or otherwise disposed of contrary to the provisions of this Act, or the laws of any State, Territory, District, or insular possession, the Court may by order direct that such articles be delivered to the owner thereof." Cong. Rec. 9380.

Section 304(d) of the 1938 Food and Drug Act contained language expressly authorizing the return of a condemned article to the owner, "to be destroyed or brought into compliance with the provisions of this Act," under FDA supervision. The addition of this language, however, was not intended to change the substance of the salvage provision. When enacting the 1938 law, which is applicable here, the Senate Report of the bill, that contained language identical to that in the present Act, stated:

> "Paragraph (d) of Section 304. "Sets forth substantially the provision of the present law concerning the condemnation of goods seized and authorization for the release of such goods under bond for reconditioning after entry of a decree of condemnation and forfeiture, where such reconditioning appears *equitable and feasible* to the Court." (Emphasis supplied)

The history of drug legislation and its judicial interpretation by the courts supports Judge Seth's dissenting opinion upholding the discretionary powers of the courts in disposing of condemned products. *Buticaps v. United States, supra; A. O. Andersen & Co. v. United States,* 284 Fed. 542 (9th Cir. 1922); *United States v. 2 Cans of Oil of Sweet Birch and 3 Cans of Oil of Gaultheria,* 268 Fed. 866 (S.D.N.Y. 1960) (Augustus N. Hand, District Judge); and *United States v. 9 Barrels of Butter,* 241 Fed. 499 (S.D.N.Y. 1917)

(Learned Hand, District Judge). The majority opinion of the court below delegates to the FDA full authority for the salvage of drugs found misbranded. We submit this is in direct conflict with the decision in *Buticaps v. United States, supra,* and the other cases cited. Under this decision it is the FDA which dictates the terms for reconditioning of condemned products, not the courts.

3. The decision of the court below relating to the "grandfather clause" (Section 107(c)(4) of the Drug Amendments of 1962) is of extreme importance to the drug industry and to the public. If the decision of the Court of Appeals stands, the effect on the drug industry will be to discourage manufacturers from putting into effect changes in labeling, however desirable they may be from the viewpoint of the public health or of scrupulous accuracy in representations to physicians and to the public, even though the changes contract the area of use represented for the drug, even though they tone down claims for the drug, even though they add warnings, and even though such improvements in the labeling are recommended by the FDA itself. The teaching of this decision is that any deviation from the October 9, 1962, labeling causes the drug to forfeit its immunity from the "new drug" procedures. Any such change would *ipso facto* subject the drug to the charge that it is a "new drug" because it is not "generally recognized" as effective, and if this charge is upheld, there is an automatic violation of the law unless and until a new drug application is filed and approved. A new drug application cannot be filed or approved until a collection of data, the requirements of which are being stiffened daily, is assembled on the basis, in most cases of new experiments, the specifications of which are also being stiffened daily.

Regulations impose continuing burdens upon the manufacturer of an NDA drug that do not apply to the manufacturer of a non-NDA'd drug. If any change in the labeling (including cut down of claims however slight) means loss of grandfatherhood and full application of new drug pro-

cedures, companies would be foolish to voluntarily change their labels to conform to the latest available evidence, for once they did,

(a) they would be subject to the one to three years' delay in approval of NDA's;

(b) they would be subject to pre-clearance of plant relocations, changes in quality control procedures and almost every aspect of drug manufacturing operations;

(c) they would be subject to periodic reporting requirements applicable to new drugs. (For a more precise listing of requirements applicable to new drugs, see Section 505 of the FD&C Act and regulations 130.4 and 130.9); and

(d) if they do not voluntarily make a label change, the FDA cannot require them to do so until such time as it could prove by a preponderance of admissible evidence in court that the drug is misbranded and is not GRAS and GRAE requiring NDA procedures. Along the same lines—once a drug is subject to new drug procedures the FDA can force manufacturers to take actions based merely upon substantial evidence of record. So long as a company is outside of new drug procedures it can only be required to take action based upon a preponderance of evidence introduced in court. If minor changes in labeling are allowed, a manufacturer would be prone to make such changes to avoid any possible product liability actions and to avoid permitting the FDA to build up by a preponderance of evidence showing that such changes in labeling should be made. Obviously this defeats the whole intent and spirit of the amendments.

In other words, the consequences of even the most benign change in labeling are so severe that many manufacturers will simply adhere to the letter of their October 9, 1962, labeling. This is directly incompatible with the FDA's plea-

for the industry voluntarily to adapt its labeling to current medical and public health standards. It is also inconsistent with the purpose of the Drug Amendments of 1962 themselves.

CONCLUSION

For the foregoing reasons, this petition for a writ of certiorari should be granted.

Respectfully submitted,

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APPENDIX A

Statutes Involved

1. Section 201(p)(1) of the Federal Food, Drug and Cosmetic Act (21 U.S.C., 321(p)(1)), provides:

> The term "new drug" means—
>
> (1) Any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such drug not so recognized shall not be deemed to be a "new drug" if at any time prior to the enactment of this Act it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

2. Section 304(a) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 334 (a)), provides:

> Sec. 304(a). Any article of food, drug, device, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce, or which may not, under the provisions of section 404 or 505, be introduced into interstate commerce, shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found: *Provided, however,* That no libel for condemnation shall be instituted under this Act, for any alleged misbranding if there is pending in any court a libel for condemnation proceeding under this Act based upon the same alleged misbranding, and not more than one such proceeding shall be instituted if no such proceeding is so pending, except that such limitations shall not apply (1) when such misbranding has been the basis of a prior judgment in favor of the United States, in a criminal, injunction, or libel for condemnation proceeding under this Act, or (2) when the Secretary has probable cause to believe from facts found, without hearing, by him or any officer or employee of the Department that the misbranded article is dangerous to health or that the labeling of the misbranded article is fraudulent, or would be in a material respect misleading to the injury or damage of the purchaser or consumer. In any case where the number of libel for condemnation proceedings is limited as above provided the proceeding pending or instituted shall, on application of the claimant, seasonably made, be removed for trial to any district agreed upon by stipulations between the parties, or, in case of failure to so stipulate within a reasonable time, the claimant may apply to the court of the district in which the seizure has been made, and such

court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business to which the case shall be removed for trial.

3. Section 304(d) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 334(d)), provides:

> (d) Any food, drug, device, or cosmetic condemned under this section shall, after entry of the decree, be disposed of by destruction or sale as the court may, in accordance with the provisions of this section, direct and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the Treasury of the United States; but such article shall not be sold under such decree contrary to the provisions of this Act or the laws of the jurisdiction in which sold: *Provided,* That after entry of the decree and upon the payment of the costs of such proceedings and the execution of a good and sufficient bond conditioned that such article shall not be sold or disposed of contrary to the provisions of this Act or the laws of any State or Territory in which sold, the court may by order direct that such article be delivered to the owner thereof to be destroyed or brought into compliance with the provisions of this Act under the supervision of an officer or employee duly designated by the Secretary, and the expenses of such supervision shall be paid by the person obtaining release of the article under bond. If the article was imported into the United States and the person seeking its release establishes (1) that the adulteration, misbranding, or violation did not occur after the article was imported, and (2) that he had no cause for believing that it was adulterated, misbranded, or in violation before it was released from customs custody, the court may permit the article to be delivered to the owner for exportation in lieu of destruction upon a showing by the

owner that all of the conditions of section 801(d) can and will be met: *Provided, however,* That the provisions of this sentence shall not apply where condemnation is based upon violation of section 402(a) (1), (2), or (6), section 501(a)(3), section 502(j), or section 601(a) or (d); *And provided further,* That where such exportation is made to the original foreign supplier, then clauses (1) and (2) of section 801(d) and the foregoing proviso shall not be applicable; and in all cases of exportation the bond shall be conditioned that the article shall not be sold or disposed of until the applicable conditions of section 801(d) have been met. Any article condemned by reason of its being an article which may not, under section 404 or 505, be introduced into interstate commerce, shall be disposed of by destruction.

4. Section 502(a) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 352(a)), provides:

Sec. 502. A drug or device shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

5. Section 107(c)(4) of the Drug Amendments of 1962 (21 U.S.C.A. Supp. fn. following Sec. 321), provides:

"(4) In the case of any drug which, on the day immediately preceding the enactment date, (A) was commercially used or sold in the United States, (B) was not a new drug as defined by section 201(p) of the basic Act as then in force (subsec. (p) of this section) made by this Act shall not apply to such drug when intended solely for use under conditions prescribed, recommended, or suggested in labeling with respect to such drug on that day."

APPENDIX B

Opinion Below

Before MURRAH, Chief Judge, and PICKETT and SETH, Circuit Judges.

MURRAH, Chief Judge

In this consolidated libel action[1] the Colorado District Court condemned as misbranded[2] a drug labeled "Halsion, A Plan of Medication and Care for Acne and Pimples" and returned the seized articles to the intervening claimant to be brought into compliance with the drug law under the supervision of a representative of the Secretary of Health, Education and Welfare.[3] This appeal is from an order of the court approving the relabeling and authorizing the marketing of the product as relabeled over the protest of the Federal Food, Drug and Cosmetic Administration.[4]

The factual issues as framed in the pre-trial order were (1) Was the Halsion Plan an adequate and effective treatment of acne and pimples; (2) Was there unanimity of opinion as to the proven value of the plan; (3) Did other remedies provide a temporary mask for skin disorders while the Halsion Plan provided lasting relief; (4) Did the Halsion tablets represent a new type of internal medication and, in conjunction with the plan, a scientific breakthrough

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[1] The Colorado suit seized for condemnation the drug in capsule form. The California suit was brought to condemn tablets of the same composition. The California suit was transferred to Colorado for purposes of trial.

[2] 21 U.S.C. §352(a)

[3] §334(d) reads in pertinent part as follows: "***the court may by order direct that such article be delivered to the owner thereof to be destroyed or brought into compliance with the provisions of this chapter under the supervision of an officer or employee duly designated by the Secretary***".

[4] The capsules were ordered destroyed and only the tablets as relabeled are involved.

in the treatment of acne and pimples; and finally, as a matter of law was the labeling misleading in any particular and, if so, misbranded within the meaning of §352(a) thus subject to condemnation under §334(d)? The claimant denies that the Halsion Plan labeling created any false or misleading impressions.

On trial of the case the Court found "That the labeling material in its net effect represented to prospective purchasers *** that the 'Halsion Plan' in and of itself is an adequate and effective treatment for acne and pimples and would give lasting relief from these conditions; that the medical profession unanimously recognizes that the 'Halsion Plan', with the exception of the Halsion pills, has proven value as an adequate and effective treatment for acne and pimples, and that the Halsion pills are 'a revolutionary new vitamin formula for internal medication' in the treatment of acne and pimples." The Court further found that "These representations were misleading in the following respects: (a) The 'Halsion Plan' in and of itself is not an adequate and effective remedy for the treatment for acne and pimples. (b) There is not a unanimity of opinion in the medical profession as to the proven value of the 'Halsion Plan', either including or excluding the taking of the Halsion pills, as an effective treatment for acne and pimples. (c) Neither the Halsion Plan nor the Halsion pills consist of 'a revolutionary new vitamin formula for internal medication' in the treatment of acne and pimples. Vitamins are prescribed by some members of the medical profession as a part of the treatment for acne and pimples. The use of vitamins for this purpose began about thirty years ago." The Court found, however, that the Halsion Plan "***may be of some benefit in mild cases of acne and pimples, and the measures prescribed in the Plan are used by some members of the medical profession, in whole or in part, in conjunction with other measures and treatments which the physician may

deem to be indicated."[5] It was accordingly concluded as a matter of law that the labeling was misbranded within the meaning of §352(a).

Amenable to the requirements of §334(d), the order returning the seized articles for relabeling expressly provided that "The Claimant shall not sell or dispose of said articles or any part thereof in a manner contrary to the provisions of the Federal Food, Drug, and Cosmetic Act***". The Court expressly retained jurisdiction for further orders deemed necessary to properly dispose of the proceedings and further provided that if by a certain date the claimant and the Secretary "***have not resolved the manner in which relabeling shall be accomplished***", the Claimant may move for an order regarding the labeling to be applied.

The Secretary's representatives and the claimant were unable to agree on the manner of relabeling. The claimant proposed to bring the condemned labeling within compliance in the following manner: "(1) The present bottle labels will be left intact and unchanged; (2) The present cartons will be left intact and unchanged; (3) All other labeling, other than advertising, introduced in the trial of the case will be destroyed. By this we mean the inserts used in both the retail and mail order packaging and all brochures now existing; (4) In lieu of the inserts in use at the time of the seizures the claimant will use an insert containing the information set forth in the exhibit attached to this letter."[6]

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[5] In the oral colloquy concerning the terms of the condemnation decree the Court expressed the informal view that the "labeling material went too far in its claims". The Court seemed to think the labeling would not have been false or misleading if, for example, it had stated "***this product may be of value or may be helpful in the treatment of mild cases of acne"; if they had eliminated the claim "***that this is a new and revolutionary product***". The Court's principal concern was "***that the labeling material gave the impression that this in itself was a complete treatment for all types of acne and pimples, and obviously from the testimony this was not true."

[6] The exhibit depicted a teenaged boy and girl and sketches of labeled containers. The insert read in pertinent part as follows: "Halsion Tablets have been scientifically formulated to help treat acne vulgaris of the comedone

(Continued on next page)

In a letter responding to the proposed relabeling the Secretary took the position that the labeling did not comply with the Court's guidelines in that (1) There was no qualification of the statement "Halsion, A Plan of Medication and Care for Acne and Pimples" and that a revision should be made to include the concept that the tablets constitute only one part of a plan and that at most "The plan may be helpful only in mild cases of acne and pimples." (2) The use of the fanciful name Halsion and the featuring of inactive ingredients on the labeling creates a misleading impression that the product is of "unique effectiveness". See

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variety and are to be used in conjunction with the recommended dietary and hygienic procedures specified in the complete Halsion Plan. *** It is with great pleasure that the Allan Drug Corporation introduces the Halsion Plan for the management and care of acne, pimples, blackheads and oily skin. The Halsion Plan consists of a program of hygienic, dietary and constitutional procedures recommended by many physicians plus a vitamin supplement in tablet form.

"The Halsion Plan

* * * *

"The Allan Drug Corporation suggests that the entire Halsion Plan be followed with regularity unless otherwise directed by your physician.

"1. Wash your face three times a day with a mild soap or soapless cleanser. Work up a rich abundant lather with hot water, gently massage the lather into your skin. Rinse thoroughly first with hot water, then with cold. Dry briskly with a clean towel.

"2. Greasy skin creams, oils or ointments should be avoided unless specifically recommended by your physician.

"3. Girls should use light make up only. Always apply face powder with a clean puff or cotton ball.

"4. Refrain from picking or squeezing pimples. Not only can this hinder the healing process, but it could spread the infection and possibly lead to permanent scarring.

"5. Dandruff has been known to aggravate an acne condition. Maintain a clean scalp. Use a good medicated shampoo and scalp conditioner.

"6. Eat a balanced diet. Avoid greasy or highly spiced foods and concentrated sweets. Many doctors discourage the eating of chocolate, nuts, iodized salt and cola drinks.

"7. Avoid constipation, upset stomach and indigestion.

"8. See your doctor and dentist regularly. Infections, such as those of tonsils or teeth, should receive prompt attention.

"9. Take two Halsion tablets daily, one in the morning and one in the evening, before or after meals or as prescribed by your physician. Do not exceed dosage.

(Continued on next page)

21 C.F.R. 1.104(c)(3). (3) The labeling should plainly state that Halsion is a vitamin supplement and nothing else. (4) The reference to Halsion tablets as scientifically formulated is not supported by any evidence and the ordinary purchaser would not understand what is meant by acne of the comedone variety. The Secretary also objected as not in conformity with the Court's guidelines to the proposed leading statement: "It is with great pleasure that the Allan Drug Corporation introduces the Halsion Plan for the management and care of acne, pimples, blackheads and oily skin. The Halsion Plan consists of a program of hygienic, dietary and constitutional procedures recommended by many physicians plus a vitamin supplement in tablet form." He took the position that in view of the order of the court reading on §334(d) to the effect that the claimant shall not sell or dispose of the article in a manner contrary to the provisions of the Act, it was necessary to evaluate the labeling in the light of all of the provisions of the Act, including §352(f)(1) re adequate directions of use. See also 21 C.F.R. 1.106(a), (o). Finally, the Secretary took the position that the requirements of §334(d) made it necessary to consider the marketing status of the Halsion tablets under the Drug Amendments of 1962, 52 Stat. 1041. In that regard the Secretary contended that having shown to the satisfaction of the Court that the drug was not generally recognized by experts as effective for its intended uses, it cannot now be legally marketed unless its effectiveness has

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"10. Get lots of sleep, plenty of sunshine, and exercise and drink plenty of water.

"Important: It must be remembered that the taking of Halsion tablets alone is not enough, you must follow the entire Halsion Plan regularly to achieve the satisfaction you desire.

"It is important to remember there are no wonder drugs or miracle cures for teen-age acne, but by following the Halsion Plan regularly you may find relief from your present acne-pimple problems. By following these simple directions, acne and pimple blemishes may be controlled, and quite possibly permanent damage can be avoided. Always remember that ordinarily a condition that has existed for a long time should not be expected to be relieved over night, however, because individual experiences may vary, the Halsion Plan is sold on a money-back guarantee. Every Halsion Plan customer must be perfectly satisfied, or his or her entire purchase price will be promptly refunded.***"

been established pursuant to a "New Drug application" in accordance with the statutory procedure set forth in 21 U.S.C. 355(a), (b).[7]

Being thus unable to agree on the relabeling, the claimant moved in accordance with the intermediate order for final approval of its proposed relabeling as "*** truthful and *** accurate in every detail***" and as in conformity with the guidelines and the Drug Act as amended. The Secretary thereupon responded to join the issues by asserting in affidavit form the same position he had taken in conference and in the supervisory letter.

Upon consideration of the motion for approval of the proposed labeling, the Court was first of the opinion that the product may be relabeled and dispensed without compliance with the "New Drug" requirements of the 1962 Amendments, i.e., §321(p)(1) and §355(a), (b). On the matter of compliance with its order, the Court approved the bottle and carton labeling, but revised the proposed inserts in some significant respects.[8]

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[7] §355(a) provides: "No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) of this section is effective with respect to such drug." Subsection (b) provides in material part that "Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a) of this section. Such person shall submit to the Secretary as a part of the application (1) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use;***"

[8] The proposed insert was revised to eliminate the words "to help treat vulgaries of the comedone variety" so that the insert read "Halsion Tablets have been formulated to help treat mild cases of acne/pimples and are to be used in conjunction with the recommended dietary and hygienic procedures specified in the complete Halsion Plan.***" The insert was also revised to add "mild cases" in the lead statement to read, "It is with great pleasure that the Allan Drug corporation introduces the HALSION PLAN for the management and care of mild cases of acne, pimples, blackheads and oily skin. ***" There were other minor or insignificant changes in the language to describe the plan. See and compare Footnote 6 for claimant's proposed labeling.

On appeal the Secretary takes sharp issue with the bottle and carton labels as approved by the Court contending that the unqualified words

HALSION

A Plan of Medication and Care for

ACNE/PIMPLES

conveys the impression to prospective purchasers, especially pathetically eager and impressionable teenagers that the Halsion Plan is adequate and effective as a remedy for acne and pimples; that such intimation is inconsistent with the conclusive findings of the Court that "***at most the Halsion Plan may be of some benefit in mild cases of acne and pimples". He has also reasserted his position with respect to the market status of the drug in view of the 1962 Amendments to §321(p)(1) and §355.

For reasons we shall attempt to demonstrate we are of the considered opinion that when, based on the facts, the trial court held the Halsion labeling false and misleading, hence misbranded, it became a "new drug" within the meaning of §321(p)(1), as amended, and was subject to the administrative procedures prescribed in §355 as amended. In this posture of the case we have no occasion to decide whether the approved relabeling complied with the orders of the Court or the Federal Drug Act. The procedures under §355 became an administrative matter in the first instance.

Prior to the 1962 Amendments, §321(p)(1) defined a "new drug" subject to the new drug procedures prescribed in §355 as "Any drug the composition of which is not generally recognized among experts***as safe for use under the conditions prescribed, recommended or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a new drug if at any time prior to the enactment of this Chapter it was subject to the Pure Food and Drug Act of 1906 as amended and if at such time its labeling contained the same representations concerning

the conditions of its use." The 1962 Amendment simply added the words "and effectiveness" after the word "safety" and the words "and effective" after the word "safe". The exception or the Grandfather Clause was perpetuated verbatim so that a drug not generally recognized as safe or effective on the date of the Amendment would not be deemed to be a new drug on that date if its labeling contained the same representations concerning the conditions of its use. Additionally, and under another and different section of the amending Act [107(a) (4)] pertaining to the effective dates of the Amendments, the Grandfather Clause was restated, "In the case of any drug which, on the day immediately preceding the enactment date (A) was commercially used or sold in the United States *** the amendments to section 201(p) *** shall not apply to such drug when intended solely for use under conditions prescribed, recommended or suggested in labeling with respect to such drug on that day." While the exempting language of the basic Act and the Amendment is verbally different, they are undoubtedly intended to mean the same thing.

Thus, as we understand the legislative scheme as amended, any drug the composition of which was not generally recognized as safe and effective under conditions recommended in its labeling was a "new drug" subject to administrative procedures prescribed in §355, except such drug was not to be deemed to be a new drug and the Amendments did not apply if the drug was intended solely for use under conditions prescribed and recommended in its labeling on the enactment date.

Soon after the 1962 Amendments, the Secretary promulgated an administrative summary in which he stated generally that safety and effectiveness of marketed drugs was the primary objective of the legislation and that it "provides new means for assuring the attainment of these objectives". Under the heading "Transitional provisions for drugs already on the market at the time of enactment", the Secretary stated in part, "As to drugs already on the market that have never been subject to the new-drug pro-

cedure but are not generally recognized as effective, the burden remains on the Government to prove in court, insofar as unchanged labeling claims are concerned, that they do not have their claimed effect. If the labeling claims are changed, however, these must be approved under the new-drug procedure."

The trial court construed the critical words "solely for use under conditions prescribed, recommended, or suggested in labeling" to mean that the Amendments should apply to a new or different area of use under conditions prescribed in the labeling. He did not think Congress intended the Amendments to apply to a mere change in the labeling after the effective date of the Act, thus imposing upon a drug manufacturer the onerous burden of the new drug procedures when, as in this case, the effect of the change in the labeling was merely to reduce the use of the drug under conditions prescribed or recommended in the labeling.

We start with the proposition that a new drug within the meaning of the Amendment is any drug the composition of which is not generally recognized as effective for use under conditions prescribed, recommended or suggested and that in our case the Secretary has proven to the satisfaction of the Court that this drug was not effective for use under conditions recommended in its labeling. It is plain, therefore, that Halsion is a new drug subject to §355 unless on the amendment date its labeling contained the same representations concerning conditions of its use, or otherwise stated, the drug was intended solely for use under conditions recommended in the labeling on the effective date.

Since we are dealing with a Grandfather Clause exception, we must construe it strictly against one who invokes it. See Spokane & Inland Empire Railroad Co. v. U. S., 241 U.S. 344, 350; McCauley v. Makah Indian Tribe, 128 F.2d 867, 869-870; 4 A.L.R.2d §1, p. 670; 50 Am.Jur. 451, Statutes §431. Then too, as we know, where Congress has empowered an administrative agency to "***initially apply a broad statutory term to a particular situation, our function is

limited to determining whether the Commission's decision "***" is warranted in the record and supported in law. See The Atlantic Refining Company v. Federal Trade Commission, 381 U.S. 357, 367; United States v. Southwest Potash Corporation, et al., August Term 1965, ...F.2d..... The trial court has a wide discretion in determining whether an article condemned under §352 may be delivered to an intervening claimant under §334(d) to be brought within compliance with the Drug Laws under the supervision of the Secretary or his delegate. See Gellman, et al. v. United States, 159 F.2d 881; 338 Cartons . . . of Butter, et al. v. United States, 165 F.2d 728; Research Laboratories v. United States, 167 F.2d 410. But, see United States v. 716 Cases . . . Del Comida Brand Tomatoes, 179 F.2d 174, in which we reversed the trial court. But, the question whether an article condemned for its false and misleading labeling has been brought within compliance of the Act is a different matter altogether. As to that, the supervisory powers committed to the Secretary undoubtedly carry broad authority to determine whether and in what manner the labeling may be brought within compliance with the act. The judicial function is concerned with the end product of the labeling process. While the final decision lies with the courts, great weight must be given to the administrative decision.

We are concerned with a condemned article, condemned because of false and misleading labeling. In determining the ultimate question whether the condemned product shall be reintroduced into commerce, we look at the fundamental purpose of the Amendments to tighten administrative control and close up loopholes to the end that the labeling on products affecting the public health and safety shall speak the truth in language that the unsuspecting purchaser can understand. See U.S. v. Articles of Drug . . . and Detroit Vital Foods, Inc., 344 F.2d 288; U.S. v. Dotterweich, 320 U.S. 277. The history of this legislation leaves no doubt of its salutary purpose to effect a change in the concept of labeling and the procedures for bringing mislabeled products into compliance. Even before the Amendment to §321(p)(1), proof to the satisfaction of the court in a libel action

that a drug was not generally recognized as safe brought the seized articles clearly within the statutory definition of a "new drug". U.S. v. 354 bulk cartons . . . Trim . . . Cigarettes, 178 F.Supp. 847; Merritt Corp. v. Folsom, 165 F.Supp. 418.

Judged in this context, we construe the critical language of the Grandfather Clauses to exempt drugs not generally recognized as effective if on the effective date of the Act the labeling contained the same representations concerning its use, and thus confine the exemptions to drugs intended solely for use under conditions prescribed on the effective date of the Act.[9] Given this interpretation, the condemned article loses the immunity of the Grandfather Clause and becomes a new drug subject to §355. This is not to say that every change in labeling must necessarily result in the manufacturer filing a new drug application to reintroduce the article into interstate commerce. It may well be that a condemned drug may be brought into compliance with the provisions of the Drug Act under the supervision of the Secretary by relabeling the article for another use for which it is generally recognized as effective, i.e. see Merritt Corp. v. Folsom, supra, where it was held that the article was a new drug even though it may not have been such if recommended for use in another disease. But, we need not speculate on the effective uses for which this article may be properly relabeled. It is enough to say that where, as here, an article has been condemned as mislabeled in fact and misbranded in law, it can be brought into compliance and reintroduced for the same or similar use only as a new drug under the procedures prescribed in §355.

Judgment is reversed, and the case is remanded with directions to proceed accordingly.

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[9] See explanation following §321 (p), Pocket Supplement, pp. 52-53, which states, "Thirdly, in the case of a drug on the market which was never subject to the new-drug procedure before, the amendments to the new-drug definition relating to drug effectiveness would not apply to existing labeling claims."

SETH, Circuit Judge, dissenting:

I differ with the conclusion reached by the majority, and feel constrained to express a contrary view in the following opinion:

The Food, Drug and Cosmetic Act of 1938 (21 U.S.C. §§ 301 and following) makes express provision that after condemnation of a drug the court may, upon the claimant furnishing bond, order that the drug be delivered to the owner to be brought into compliance with the provisions of the Act. This compliance is to be under the supervision of an employee of the Administration (21 U.S.C. § 334(d)). This procedure is intended by Congress to be used by the courts when in their discretion a salvage of the drug is possible through some change in the product or label. The Act contemplates that the court enter an order requiring such action to be taken.

The law thus provides for what is commonly referred to as a salvage of the condemned drug. This is a remedy available to the claimant in judicial proceedings which are then pending when the court in the exercise of its discretion determines that salvage is proper. This is an important and much used provision of the Act, vesting in the courts the post-condemnation authority over destruction or salvage. This exists independently of any administrative functions of the agency.

The Government here seeks to eliminate this judicial remedy through its construction of other sections of the Act which were amended in 1962. The provision for salvage has been in effect since at least 1938, and the section providing for it was not amended in 1962.

The trial court in the instant case used the statutory salvage authority and set up guidelines for relabeling the product under agency supervision and cooperation. There was no finding nor real contention that the drug in question was in any way harmful, dangerous, or adulterated. Instead it

simply did not live up to the claims made in its labeling as to its effectiveness, but was found by the court to be effective in certain circumstances.

The appellee pursuant to the court's order in conferences with the agency made proposals for changes in labeling to bring the drug into compliance. The agency replied to the proposals in some detail, refusing to agree, but concluded by saying: "However, because the Court found that the article was misbranded . . . thus rendering relabeling necessary, we believe that the 'grandfather clause' no longer applies, this for the reason that under any revised labeling, the product would no longer be intended 'solely for use under conditions prescribed, recommended, or suggested in labeling with respect to such drug' on October 9, 1962, which is the cut-off date under the 'grandfather clause' exception."

Thus apparently no relabeling was possible with the cooperation of the Food and Drug Administration because it relied on its legal opinion, expressed above, to the effect that under *no revised labeling* could the product be marketed under the salvage provisions of the Act. Thus the trial court entered an order for relabeling. This action the Government now says constituted an overruling of "the administrative determinations and substituted those of the Court." It is difficult to see how this argument could be made in view of the fact that the administrative determination was in reality one of law, and the court substituted its opinion. The Government in its brief discusses at length the agency's functions in salvage proceedings, but again this has little significance when it took the position that no salvage was possible under its construction of the Act.

The 1962 amendments to 21 U.S.C. § 321(p)(1) and § 355 brought about substantial changes in the scope of these certain sections of the statute, especially in relation to the definition of new drugs. Where the law had theretofore applied to drugs not generally recognized as "safe," it was extended by the addition of words "and effective" or "and effectiveness" after the words "safe" or "safety" to include the matter of whether the drug was efficacious. Upon

such an issue the burden of persuasion and time expended to persuade became particularly important, as is demonstrated by the position taken by the parties in this case. The Government would have the appellee drug company climb the administrative vine from the bottom, while appellee, having lost the libel portion of the case, sought instead and obtained the judicial salvage remedy under 21 U.S.C. § 334(d) in the court where the proceedings were already pending.

If we confine our analysis to the 1962 amendments and especially as they changed the section defining a "new drug" (21 U.S.C.A: § 321(p)(1)), the logic of the Government's argument is persuasive. Under Section 321(p)(1), a drug *not* recognized as effective is *not a* "new drug" if among other things its labeling prior to the amendment date " . . . contained the same representations concerning the conditions of its use" as at the time in question. A drug is thereby possibly confined to the exact labeling used on the effective date of the amendment of 1962, and if any deviations thereafter occur or are required, the drug may automatically become a "new drug." Thus under the Government's argument the appellee's labeling claims were found by the trial court to be false, a change was necessary; and therefore, it was not, or would not be, as labeled on the effective date of the amendment of 1962; therefore, it was a "new drug"; therefore, administrative application under § 355 was required and appellee was thus required to start anew the administrative procedure to qualify to sell at all.

When this analysis is followed, it is to entirely ignore 21 U.S.C. § 334(d), above described, and to assume that it has been rendered ineffective as to this case by the amendment of other sections. It is difficult to see how it could have been so changed when nothing in the legislative history indicates any intention to eliminate a judicial remedy under the circumstances of this case. H.R. Rep. No. 2464, 87th Cong., 2d Sess.; Cong. Record Senate, August 23, 1962, p. 16305, note following 21 U.S.C.A. § 321.

The construction urged also prevents any maker of a drug, presently under the grandfather clause, from changing the label to even reduce the claim of effectiveness should new information become available or for any other good reason a change to conform to the facts should be made. It would seem that the purpose of the Act is to encourage label corrections rather than to discourage them.

Instead a construction of the 1962 amendments should be adopted which preserves the remedies in the portions of the Act not amended and not intended to be changed. The trial court did this under a construction which generally considers the words, "conditions of use," in 21 U.S.C. § 321(p)(1) as used in the Act to refer to the general purposes for which the drug is to be used, and not to specific claims of effectiveness. Thus there was no change in the case at bar as to "conditions of use."

On this point the case of Merritt Corp. v. Folsom, 165 F.Supp. 418, cited by the Government, shows the position of the Food and Drug Administration under the old wording relating to "safe." There the question was the application of an old drug preparation to a new use or new disease. It was held that the new use made it a new drug for that purpose. This was a new "condition of use" as above described. The Government refers also to the case of United States v. 354 Bulk Cartons . . . Trim Reducing-Aid Cigarettes, 178 F.Supp. 847, where the real question was whether the cigarettes were a drug, the claimant contending they were not. The court found they were a drug and hence by the same finding they had to be new since claimant had not maintained they were a drug at all. These two cases, in my opinion, do not hold that under the old section an unsafe drug has been held to be a "new drug," nor is there authority that an ineffective drug is a "new drug."

Instead of the trial court's view, which has much to recommend it, I would construe 21 U.S.C. § 334 relating to judicial salvage orders as not being inferentially limited by the amendment of 1962 to 21 U.S.C. § 321(p)(1) relating to the definition of new drugs. I would hold that involuntary

label changes are not contemplated by Section 321(p)(1) when ordered as a part of a court's salvage decision and order. Such changes cannot be those contemplated in the new drug definition simply because no intention appears to eliminate judicial salvage in situations such as the one before us. If the contention of the Food and Drug Administration is adopted, the United States District Court when it has exercised its discretion to order salvage, as here by relabeling, thereby loses jurisdiction to proceed under the statute. The salvage is thereby thwarted. Or if the Government's view is adopted, it may be said that the court's order to relabel is then subject to administrative review by the requirement that the claimant start anew through administrative channels. In either view the statutory judicial remedy is eliminated.

A construction should be followed which would give effect to both sections; and this may be done, as above described, by construing Section 321(p)(1) as not applicable to involuntary relabeling as part of the court's salvage order. This is entirely reasonable and proper, and would carry out the intentions of the Act and also preserve the intended relationship between judicial and administrative functions.

I would affirm.

APPENDIX C

Conflicting Opinion

Buticaps, Inc. v. United States of America, 252 F.2d 634. (United States Court of Appeals, District of Columbia, January 30, 1958.)

Before PRETTYMAN, WILBUR K. MILLER and BASTIAN, Circuit Judges.

PER CURIAM.

The libel in this case was filed to condemn certain articles of drug (a claimed skin conditioner) in accordance with the

Federal Food, Drug and Cosmetic Act.[1] It was claimed that the articles were misbranded within the meaning of said Act in that: (1) as alleged in paragraph 3 of the libel a leaflet entitled "Buticaps" enclosed in each package, and a booklet entitled "here's how * to promote * to sell * to profit with Buticaps" contained statements which were false and misleading; and (2) as alleged in paragraph 4 of the libel the aforementioned articles were further misbranded in that the designations of certain vitamins and proteins appearing on the package labels were false and misleading.

Thereafter, the libel was amended by adding paragraph 3(a) to allege that the name "Buticaps" on the package labels, leaflet and booklet represents and implies that the articles will beautify the skin of the user, which is false and misleading since the articles will not beautify the skin of the user.

After answer by libelee admitting the allegations in paragraphs 3 and 4 of the libel but denying the allegations in paragraph 3(a) as to the use of the word "Buticaps,"[2] the Government filed motion for judgment on the pleadings. This motion was not opposed but, in the answer thereto, libellee [claimant] urged: "If this Motion is granted, claimant's pleading with regard to the name 'Buticaps' must be taken as true."

The District Court filed a memorandum announcing that it would grant the motion for judgment on the pleadings but would exercise its discretion in not ordering the articles destroyed, as it had a right to do,[3] and would release the seized articles for relabeling. The court's memorandum contained the following language:

> "* * * Provided, however, that the claimant post a good and sufficient bond to insure compliance with the statute and that relabeling is done under the su-

[1] 21 U.S.C.A. §§ 301-392 (1952).

[2] It was claimed by 'ibelee in its answer that that name was "neither false nor misleading since it is a coined word which has no meaning aside from the meaning given it by naming this product."

[3] 21 U.S.C.A. § 334(d).

pervision of an officer or employee duly designated by the Secretary of the Department of Health, Education and Welfare, as the statute provides, the expenses of such supervision to be paid by the claimant. The Court regards these provisions as mandatory. "Order accordingly."

Thereupon, on February 19, 1957, the court ordered that judgment on the pleadings be entered in favor of plaintiff [libelant].

On February 28, 1957, libelee moved the court for an order directing that the condemned articles be delivered to libelee and requesting that the court specify, pursuant to the judgment on the pleadings, that the statute was found to have been violated in the following manner and only in the following manner:

"(1) Misbranding in reference to a leaflet entitled 'Buticaps,' enclosed in each package of the condemned article;

"(2) Misbranding in reference to two designations appearing on the label of the seized articles."

Libelee asked that the court "further specify that the seized articles must now be brought into compliance with the Federal Food, Drug and Cosmetic Act * * * by appropriate relabeling but that, pursuant to the aforesaid judgment, there has been no judicial determination in this action that the name 'Buticaps' does not comply with the statute, which name need, therefore, not be changed under the judgment entered heretofore in this action."

The Government's reply to the motion stated that the position of the *Department of Health, Education and Welfare* was that the name "Buticaps" is false and misleading, and that it would be a violation of the statute to allow relabeling under that name. Thereupon, on May 21, 1957, the court entered its order, reciting, among other things, that because of libelee's insistence upon the use of the name "Buticaps," further efforts to relabel would be fruitless;

and the court directed that the articles seized be destroyed by the United States Marshal. This appeal followed.

[1] We think this ruling of the District Court was erroneous. The judgment on the pleadings was limited, of necessity, to the admitted facts. We believe that the refusal of the Department of Health, Education and Welfare to allow relabeling unless the word "Buticaps" was eliminated was unauthorized, and that libelee was entitled to a *judicial* hearing and ruling on the question of the alleged misuse of the word. See Ewing v. Mytinger & Casselberry, 339 U.S. 594, 70 S.Ct. 870, 94 L.Ed. 1088 (1950).

[2] We agree that, as the Government contends, "[b]y violating the law and introducing a misbranded drug into interstate commerce, the owner of the article, after there has been a judicial determination that the article violates the law, loses any *right* to repossess his property" and that "[h]e regains the property upon such terms and conditions as to the trial court seem just and proper, within the confines of the powers conferred by Section 304(d)" of the Act [21 U.S.C.A. § 334(d)]. But the terms and conditions are to be fixed by the *court* and not by the Department of Health, Education and Welfare. Libelee is entitled to judicial due process.

It is no answer, as urged by libelant, to say that the name "Buticaps" itself implies that the article will impart beauty. It may be that, on hearing, the court, on evidence, could determine that the use of the name "Buticaps" is misleading. As to this, we express no opinion.

Accordingly, the judgment of the District Court is reversed; and the case is remanded to that court, either to proceed to the judgment of relabeling, insofar as the admitted violations are concerned, or, if the court be so advised, to re-open the case to determine the issue as to the use of the word "Buticaps."[4]

Reversed and remanded.

[4] It is noted that libelant, at the hearing on the motion of libelee to relabel the condemned articles, orally moved that the case be reopened for the purpose of trial on "the merits of that one issue."

INDEX

	Page
Opinions below	1
Jurisdiction	1
Question presented	2
Statute involved	2
Statement	2
Argument	5
Conclusion	10
Appendix	11

CITATIONS

Cases:

Buticaps, Inc. v. *United States*, 252 F. 2d 634	7, 8
Hipolite Egg Co. v. *United States*, 220 U.S. 45	8
Research Laboratories, Inc. v. *United States*, 167 F. 2d 410, certiorari denied, 335 U.S. 843	7
United States v. *Dotterweich*, 320 U.S. 277	6
United States v. *Kent Food Corp.*, 168 F. 2d 632, certiorari denied, 335 U.S. 885	7
United States v. *716 Cases * * * Del Comida Brand Tomatoes*, 179 F. 2d 174	7
United States v. *354 Bulk Cartons * * * Trim Reducing-Aid Cigarettes*, 178 F. Supp. 847	9

Statutes:

Drug Amendments of 1962, Section 107(c)(4), 76 Stat. 789	5, 6, 11
Federal Food, Drug, and Cosmetic Act 52 Stat. 1040, as amended, 21 U.S.C. 301, *et seq.*:	
21 U.S.C. 321	5, 11
21 U.S.C. 334	3, 7, 11
21 U.S.C. 352	12
21 U.S.C. 355	5, 8, 12

231-503—66

In the Supreme Court of the United States

OCTOBER TERM, 1966

No. 372

ALLAN DRUG CORPORATION, PETITIONER

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE TENTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

OPINIONS BELOW

The majority and dissenting opinions of the court of appeals (Pet. 17–32) are reported at 357 F. 2d 713. The findings of fact and conclusions of law of the district court (R. 23–27) are not reported.

JURISDICTION

The judgment of the court of appeals was entered on February 18, 1966. A petition for rehearing was denied on April 29, 1966. The petition for a writ of certiorari was filed on July 20, 1966. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

QUESTION PRESENTED

The "grandfather clause" of the Drug Amendments of 1962 exempts from the requirement that promotional claims be supported by substantial evidence of effectiveness drugs commercially available on the date of enactment, if the drug was "intended solely for use under conditions prescribed, recommended, or suggested in labeling with respect to such drug on that day." The claims for the drug here involved—which were in use on the date of enactment—have been adjudged false and misleading, and labeling revision is required to bring the article into compliance with law. The question presented is whether the grandfather clause excuses the drug company from the requirement of proof of effectiveness of the revised labeling.

STATUTE INVOLVED

The pertinent provisions of the Federal Food, Drug, and Cosmetic Act and of the Drug Amendments of 1962 are set forth in the Appendix, *infra*, pp. 11–13.

STATEMENT

This was a seizure action *in rem* under the Federal Food, Drug, and Cosmetic Act involving Halsion Tablets, a multi-vitamin preparation distributed by petitioner (R. 55, 120–121). The drug was alleged to be misbranded because its labeling made false and misleading claims regarding its effectiveness as a treatment for acne and pimples. After a trial, the district court found that the labeling contained repre-

sentations to prospective customers that were false and misleading (R. 26):

> (a) The "Halsion Plan" in and of itself is not an adequate and effective remedy for the treatment for acne and pimples.
>
> (b) There is not a unanimity of opinion in the medical profession as to the proven value of the "Halsion Plan", either including or excluding the taking of the Halsion pills, as an effective treatment for acne and pimples.
>
> (c) Neither the Halsion Plan nor the Halsion pills consist of "a revolutionary new vitamin formula for internal medication" in the treatment of acne and pimples. Vitamins are prescribed by some members of the medical profession as a part of the treatment for acne and pimples. The use of vitamins for this purpose began about thirty years ago.

The district court entered a decree of condemnation which adjudged the drug to be misbranded and directed that the drug be returned to the petitioner to be relabeled under the supervision of the Food and Drug Administration (R. 27–30). Paragraph 6 of that decree provided, in accordance with 21 U.S.C. 334(d) (R. 29), that:

> The Claimant shall not sell or dispose of said articles * * * in a manner contrary to the provisions of the Federal Food, Drug, and Cosmetic Act * * *.

One of the principal objections to the proposed labeling revisions was their failure to comply with the new-drug requirements of the law added by the Drug Amendments of 1962 (R. 52–53).

Nevertheless, on motion of petitioner, the district court entered an Order For Relabeling (R. 59–60) which decreed that the product may be relabeled and dispensed without compliance with the Drug Amendments of 1962 and approved labeling to be used for future promotion of the drug which permits continued and unqualified use of the original bottle and carton labels (R. 55), including a package insert which states in part (Pet. 22, n. 8):

> Halsion Tablets have been formulated to help treat mild cases of acne/pimples * * *.

This language was approved because of the district court's finding (R. 26–27) that:

> 4. The "Halsion Plan" may be of some benefit in mild cases of acne and pimples, and the measures prescribed in the Plan are used by some members of the medical profession, in whole or in part, in conjunction with other measures and treatments which the physician may deem to be indicated. There is no evidence that any members of the medical profession use or recognize the Halsion Plan in and of itself as an adequate and effective treatment for acne and pimples.

The Court of Appeals for the Tenth Circuit reversed, one judge dissenting. The Court held that, as a result of the labeling changes required by condemnation, the drug lost the immunity of the grandfather clause in the Drug Amendments of 1962. It stated (Pet. 27, 357 F. 2d at 719):

> [W]e construe the critical language of the Grandfather Clauses to exempt drugs not gen-

> erally recognized as effective if on the effective date of the Act the labeling contained the same representations concerning its use, and thus confine the exemptions to drugs intended solely for use under conditions prescribed on the effective date of the Act. * * *

Since the labeling approved by the district court after condemnation was not the same as the original labeling, the court ruled that the drug was no longer "intended solely for use under conditions prescribed on the effective date of the Act." Consequently, the grandfather clause no longer applied, and the drug ceased to be exempt from the "new drug" definition in 21 U.S.C. 321(p)(1) and could be marketed only on the basis of proven effectiveness in compliance with 21 U.S.C. 355 (Pet. 27, 30, 357 F. 2d at 719, 721).

ARGUMENT

The central purpose of the Drug Amendments of 1962 is to prevent exploitation of the consumer through unproven remedies of dubious value. To this end, the Amendments establish a procedure for proving the effectiveness of new drugs. Petitioner's Halsion Tablets are plainly a new drug within the meaning of the Amendments (see pp. 8–9, *infra*), and the only question is whether this drug is exempt from the new-drug requirements by virtue of Section 107(c)(4)—the "grandfather clause"—of the Amendments. The court below correctly found that it was not. As the court of appeals rightly pointed out (Pet. 25, 357 F. 2d at 718), "Since we are dealing with a Grandfather Clause exception, we must construe it strictly against

the one who invokes it." It would be improper to read "an exception to an important provision safeguarding the public welfare with a liberality which more appropriately belongs to enforcement of the central purpose of the Act." *United States* v. *Dotterweich,* 320 U.S. 277, 284. The exemption of Section 107(c)(4) applies only if the drug is intended solely for use under conditions recommended in the labeling of the drug at the time the Amendments were passed. Since the labeling of Halsion Tablets was found to be false and misleading, the drug may no longer be sold for use as suggested in the labeling that was in force at the time of the enactment of the Drug Amendments, and it is therefore not within the terms of the exemption.

Petitioner contends that the court of appeals' construction will deter drug manufacturers from voluntarily changing their labeling to make it more accurate and less misleading. But that is not this case. Petitioner's labeling was found in a judicial proceeding to be false and misleading; it was only under compulsion of law that the labeling was changed. We submit that a change of labeling required because of a manufacturer's violation of law is not a shield against compliance with the requirements of the Drug Amendments.

Petitioner also contends that the decision below improperly limits the district court's discretionary power to permit the salvage, rather than destruction, of condemned drugs. However, the power of the district court to return a condemned drug to the

manufacturer is operative only where the drug can be brought into full and unequivocal compliance with all of the provisions of the Federal Food, Drug, and Cosmetic Act. 21 U.S.C. 334(d); *United States* v. *Kent Food Corp.*, 168 F. 2d 632, 634–635 (C.A. 2), certiorari denied, 335 U.S. 885; *Research Laboratories, Inc.* v. *United States*, 167 F. 2d 410, 422–423 (C.A. 9), certiorari denied, 335 U.S. 843; *United States* v. *716 Cases . . . Del Comida Brand Tomatoes*, 179 F. 2d 174, 175 (C.A. 10). The key limitation of the district court's discretionary power to permit salvaging of a condemned article is the statutory condition that the article is "to be destroyed or *brought into compliance with the provisions of this chapter.*" 21 U.S.C. 334(d) (emphasis added). The scope of the district court's discretion is not fixed as of 1938 when Section 334(d) was enacted, but may be affected by any legislative change in the "provisions of this chapter" though such change may not make specific reference to Section 334(d). When the district court exercised its discretionary power in this case on October 2, 1964 (R. 59), its power was limited by the Drug Amendments of 1962 as well as all other amendments to the basic Act of 1938 that were in effect on October 2, 1964.

Petitioner alleges but in no way shows a conflict between the decision below and *Buticaps, Inc.* v. *United States* (Pet. App. C, 252 F. 2d 634 (C.A. D.C.)). Both decisions hold that the courts rather than the administrative agency must make the final decision as to the terms and conditions of salvage-

ability of a condemned product; otherwise, they are completely unrelated.[1] In the instant case the court of appeals held only that the district court had exceeded its statutory authority when it authorized a salvage operation which did not conform to the 1962 law. No such issue was involved in *Buticaps*.

Petitioner contends finally that the decision below deprives it of property without due process of law. But its drug was condemned by the district court only after a full trial in which the drug was found to be misbranded by reason of false and misleading labeling. By the judicial process, petitioner's pills were adjudicated to be "outlaws of commerce" (*Hipolite Egg Co.* v. *United States*, 220 U.S. 45, 58) and petitioner then lost the right to regain the property. Nor is there any merit to the suggestion that the question of the effectiveness of Halsion Tablets was not adequately canvassed. Under the Drug Amendments, a drug whose effectiveness is not generally recognized by qualified experts is a "new drug" and it may not be marketed commercially until its sponsor has demonstrated its effectiveness by substantial evidence in an administrative proceeding. 21 U.S.C. 355. No further hearing is required to demonstrate that Halsion Tablets are not generally recognized by

[1] The dissenting opinion is mistaken in stating that the Food and Drug Administration "took the position that no salvage was possible under its construction of the Act." (Pet. 29, 357 F. 2d at 720–721). In fact the agency pointed out that there were three possible methods of salvage (R. 54), and it indicated a readiness to consider any proposals petitioner might make for bringing the article into compliance with the Act (R. 53).

qualified experts as effective for the purposes stated in the revised labeling, namely (1) "to help treat mild cases of acne/pimples," and (2) "for the management and care of mild cases of acne, pimples, blackheads and oily skin" (Pet. 22, n. 8; 357 F. 2d at 717). Condemnation of the drug was predicated upon an ample showing that it is not an adequate and effective remedy for acne and pimples. The district court's finding in approving the revised labeling that "the Halsion Plan may be of some benefit in mild cases of acne and pimples" (R. 26) is merely a conjectural statement of possible benefit—yet it reflects the very best that can be said for the drug. The evidence is clear that the drug is not generally recognized by qualified experts as effective in the treatment of any kind of acne and pimples, mild or severe.[2]

---

[2] Dr. Cornbleet, an outstanding dermatologist, testified that Vitamin A has had its vogue in the treatment of acne and that the vast majority of doctors no longer use it (R. 143). Dr. Buchholz testified that Vitamin A was not even mentioned as a treatment for acne at the last meeting of the International Congress on Dermotology (R. 100). Dr. Perlstein, called by the defense, testified (R. 186): "I don't think the medical profession knows the Halsion Plan." She also testified (R. 187): "There is a definite controversy among us dematologists about the use of vitamins in the internal treatment of acne vulgaris." She stated she knew of no controlled clinical studies that have been performed by the use of Halsion Tablets (R. 188). The existence of such a controversy alone establishes that the drug is not "generally recognized" as effective by qualified experts and "brings the seized articles clearly within the statutory definition of a new drug." *United States v. 354 Bulk Cartons * * * Trim Reducing-Aid Cigarettes*, 178 F. Supp. 847, 853 (D. N.J.).

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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SEPTEMBER 1966.

APPENDIX

Section 107(c)(4) of the Drug Amendments of 1962, 76 Stat. 789 provides:

> In the case of any drug which, on the day immediately preceding the enactment date, (A) was commercially used or sold in the United States, (B) was not a new drug as defined by section 201(p) of the basic Act as then in force, and (C) was not covered by an effective application under section 505 of that Act, the amendments to section 201(p) made by this Act shall not apply to such drug when intended solely for use under conditions prescribed, recommended, or suggested in labeling with respect to such drug on that day.

Section 201 of the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1041, as amended, 21 U.S.C. 321, provides:

> For the purposes of this Act—
>
> * * * * *
>
> (p) The term "new drug" means—
>
> (1) Any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety *and effectiveness* of drugs, as safe *and effective* for use under the conditions prescribed, recommended, or suggested in the labeling thereof * * *.

(Italicized matter added by 1962 amendments.)

Section 304 of the Act, 21 U.S.C. 334, provides:

> (a) Any article of * * * drug * * * that is * * * misbranded * * * shall be liable to be * * * condemned * * *.
>
> * * * * *

(d) Any * * * drug * * * condemned under this section shall * * * be disposed of by destruction or sale * * * *Provided,* That after entry of the decree and upon the payment of the costs of such proceedings and the execution of a good and sufficient bond conditioned that such article shall not be sold or disposed of contrary to the provisions of this chapter or the laws of any State or Territory in which sold, the court may by order direct that such article be delivered to the owner thereof to be destroyed or brought into compliance with the provisions of this chapter under the supervision of an officer or employee duly designated by the Secretary * * *.

Section 502 of the Act, 21 U.S.C. 352, provides:

A drug * * * shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

Section 505 of the Act, 21 U.S.C. 355, provides:

(a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) of this section is effective with respect to such drug.

(b) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a) of this section. Such person shall submit to the Secretary as a part of the application (1) full reports of investigations which have been made to show whether or not such drug is safe for use *and whether such drug is effective in use;* (2) a full list of the articles used as components of such drug; (3) a full statement of the composition of such drug; (4) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing,

and packing of such drug; (5) such samples of such drug and of the articles used as components thereof as the Secretary may require; and (6) specimens of the labeling proposed to be used for such drug. (Italicized matter added by 1962 amendments.)

U.S. GOVERNMENT PRINTING OFFICE: 1966